A3

3. (amended) The compound of claim 1 further comprising a sFv of monoclonal antibody H22 which is a humanized anti-CD64 antibody.

REMARKS

Claims 1-5 are pending in this application. Claims 4 and 5 have been withdrawn from consideration. Claims 1-3 have been rejected. Claim 2 has been canceled. Claims 1 and 3 have been amended. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Election/Restriction Requirement Under 35 U.S.C. 121

The restriction requirement placing the claims into Groups I-III has been deemed proper and made final. Accordingly, Applicants are canceling claims 4 and 5 without prejudice, reserving the right to file continuing applications for the canceled subject matter.

II. Sequences

The Examiner has suggested that the application fails to comply with the requirements of 37 CFR 1.821(a)(1) and (a)(2)because at page 4, line 24, no SEQ ID NO. is listed for the

linker. Applicants respectfully point out that the linker is given a SEQ ID NO. and is in fact described starting at line 28, including using SEQ ID NO: 5. In order to clarify this, Applicants have amended the specification at line 24 to also refer to this SEQ ID NO.

III. Drawings

The drawings as filed on January 22, 2002 are stated to be not approved. Applicants are filing herewith corrected drawings as required.

IV. Rejection of Claims Under 35 U.S.C. 112, First Paragraph

Claim 1 has been rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. The Examiner suggests that the specification does not describe a composition comprising a baculovirus expressing any recombinant Fel dI but instead only one comprising chain-1 Fel dI and chain-2 linked together in series via a flexible peptide linker and then

linked to sFv H22. Applicants respectfully traverse this rejection.

Applicants have amended claim 1 to recite the limitations set forth in claim 2 which include chain 1 and chain 2 expressed in series and linked together by a glycine/serine linker. Claim 2 has been canceled. Accordingly, withdrawal of this rejection is respectfully requested.

V. Rejection of Claims Under 35 U.S.C. 112, Second Paragraph

Claims 1-3 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner suggests that recitation of "a composition" is indefinite and suggests use of "a compound". The Examiner also suggests that use of "sFv of monoclonal antibody H22" is indefinite because "antibody H22" is a laboratory designation. Applicants have canceled claim 2 and amended claim 1, and by dependency claim 3, to recite "a compound" as suggested by the Examiner. Applicants have then amended claim 3 to recite that H22 is the humanized anti-CD64 antibody, as defined at page 2, lines 7-8. Withdrawal of this rejection is therefore respectfully requested.

VI. Rejection of Claims Under 35 U.S.C. 102(b)

Claim 1 has been rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,547,669. The Examiner suggests that this patent discloses a recombinant cat allergen Fel dI fusion protein comprising chains 1 and 2 linked together. Applicants respectfully traverse this rejection.

US Patent 5,547,669 discloses recombinant peptides have T cell stimulating activity and includes cat allergen Fel dI fusion proteins. However, nowhere does this patent teach or suggest the specific recombinant compound as claimed which is a baculovirus expressed recombinant Fel dI comprising chain 1 and chain 2 expressed in series and linked by a glycine/serine linker. In order to anticipate an invention the reference must teach each and every limitation of the claims (MPEP 2131). Accordingly, this patent cannot anticipate the claim as amended and withdrawal of this rejection is respectfully requested.

VII. Rejection of Claims Under 35 U.S.C. 103(a)

Claims 2 and 3 have been rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,547,669, in view of US Patent 5,837,243. The Examiner suggests that it would have been prima

facie obvious for one of ordinary skill to link chain 1 and chain 2 as taught in the '669 patent using a linker such as glycine and serine as taught in the '249 patent and further linked to a sFv monoclonal antibody H22 as taught in the '243 patent to result in the instant invention. The Examiner suggests that motivation is provided by the teaching of the '243 patent. Applicants respectfully traverse this rejection.

At the outset, Applicants have canceled claim 2 and amended claim 3 to depend from claim 1. As discussed *supra*, US Patent 5,547,669 discloses recombinant peptides having T cell stimulating activity and includes cat allergen Fel dI fusion proteins. However, nowhere does this patent teach or suggest the specific recombinant compound as claimed which is a baculovirus expressed recombinant Fel dI comprising chain 1 and chain 2 expressed in series and linked by a glycine/serine linker.

US Patent 5,837,243 discloses compounds comprised of anti-Fc receptor antibodies including multi-specific molecules that can be designed against many antigens. Although the patent discloses making bi-specific molecules encoding single chain antibody H22 that is specific for humanized Fc receptor such as FcγRI, nowhere does this patent teach or suggest the specific compound of the instant invention which is a baculovirus expressed recombinant Fel

dI comprising chain 1 and chain 2 expressed in series and linked by a glycine/serine linker. The Examiner points to figure 40A and suggests that the glycine/serine linker is taught in this patent. Although figure 40A does show use of a linker that includes $(Gly_4Ser)_3$, nowhere, including Figures 39A, 39B, 40A, 40B and 40C, does this patent show use of a linker comprising SEQ ID NO:5 of the instant specification. Figure 40A shows a linker present but does not define where it stops. Further, this patent fails to provide any data which would allow one of skill to expect that the specific compound of the instant invention would be successfully used. It is only with the specification in hand that one of skill is able to see that the specific invention of a baculovirus expressed recombinant Fel dI comprising chain 1 and chain 2 expressed in series and linked by a glycine/serine linker is biologically useful.

To establish a *prima facie* case of obviousness, three basic criteria must be met. MPEP 2143. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art must teach or suggest all claim limitations.

Clearly, the combination of prior art cited fails to teach or suggest the limitations of the claims as amended, which claim a baculovirus-expressed, recombinant Fel dI comprising chain 1 and chain 2 expressed in series and linked by a glycine/serine linker, and thus cannot render the instant claimed invention obvious. There is also no expectation of success provided in the cited combination of references. Further, there is no suggestion in the references cited to combine the teachings of these references as required under MPEP 2143.01. Accordingly, withdrawal of this rejection is respectfully requested.

Claim 1 has been rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,547,669, in view of Bei et al. (1995). The Examiner suggests that it would have been *prima facie* obvious for one of ordinary skill to substitute the *E. coli* expression vector of the '669 patent for the baculovirus expression vector of Bei et al. for a composition comprising a baculovirus-expressed, recombinant Fel dI. Applicants respectfully traverse this rejection.

Applicants have amended claim 1 to recite that the Fel dI comprises chain 1 and chain 2 expressed in series and linked by a glycine/serine linker. As discussed *supra*, the '669 patent fails to teach or suggest this specific Fel dI. Bei et al. (1995)

describes baculovirus expression of an IL-2 fusion protein. Nowhere does this paper teach or suggest a Fel dI chain 1 and chain 2 expressed in series and linked by a glycine/serine linker using baculovirus. Therefore, this combination of art fails to teach the limitations of the claims as required under 35 U.S.C. 103(a). Accordingly, withdrawal of this rejection is respectfully requested.

Claims 2 and 3 have been rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,547,669, in view of Bei et al. (1995) and further in view of US Patent 5,837,243. The Examiner suggests that it would have been prima facie obvious for one of ordinary skill in the art to link chain 1 and chain 2 as taught in the '669 patent using a linker such as glycine and serine as taught in the '243 patent and further linked to a sFv monoclonal antibody H22 as taught in the '243 patent for a composition comprising the baculovirus expressed compound of the instant invention. The Examiner suggests that motivation is provided by the '243 patent and the paper of Bei et al. (1995). Applicants respectfully traverse this rejection.

US Patent 5,547,669 discloses recombinant peptides having T cell stimulating activity and includes cat allergen Fel dI fusion proteins. However, nowhere does this patent teach or suggest the

specific recombinant compound as claimed which is a baculovirus-expressed, recombinant Fel dI comprising chain 1 and chain 2 expressed in series and linked by a glycine/serine linker.

US Patent 5,837,243 discloses compounds comprised of anti-Fc receptor antibodies including multi-specific molecules that can be designed against many antigens. Although the patent discloses making bi-specific molecules encoding single chain antibody H22 that is specific for humanized Fc receptor such as FcγRI, nowhere does this patent teach or suggest the specific compound of the instant invention which is a baculovirus-expressed, recombinant Fel dI comprising chain 1 and chain 2 expressed in series and linked by a glycine/serine linker. The Examiner points to Figure 40A and suggests that the glycine/serine linker is taught in this patent. Although Figure 40A does show use of a linker that includes $(Gly_4Ser)_3$, nowhere does this patent show use of a linker limited to that sequence and as taught in the instant specification. Figure 40A shows a linker present but does not define where it stops so that one of skill would not know whether the linker is the same as that of the instant invention. Further, this patent fails to provide any data which would allow one of skill to expect that the specific compound of the instant invention would be successfully used. It is only with the specification in hand that

one of skill is able to see that the specific invention of a baculovirus expressed recombinant Fel dI comprising chain 1 and chain 2 expressed in series and linked by a glycine/serine linker is biologically useful.

Bei et al. (1995) discloses baculovirus expression of a an IL-2 fusion protein. Nowhere does this paper teach or suggest a Fel dI chain 1 and chain 2 expressed in series and linked by a glycine/serine linker using baculovirus. Therefore, this paper would also fail to teach the instant invention as well as failing to provide one of skill with the expectation of success for use of baculovirus to express the specific compound of the instant invention. Again, it is only with the specification in hand that one of skill is able to see that the compound of the instant invention is active and useful.

To establish a *prima facie* case of obviousness, three basic criteria must be met. MPEP 2143. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art must teach or suggest all claim limitations.

In order to advance the prosecution and facilitate allowance of the claims, Applicants have amended claim 1 to recite the SEQ ID NO. of the linker used in the instant invention. None of the cited references teach this linker. Therefore, clearly, the combination of prior art cited fails to teach or suggest the limitations of the claims as amended, which claim a baculovirus expressed recombinant Fel dI comprising chain 1 and chain 2 expressed in series and linked by a glycine/serine linker of SEQ ID NO: 5, and thus cannot render the instant claimed invention obvious. Further, and as discussed *supra*, there is also no expectation of success provided in the cited combination of references. The art of development of antibodies to allergens is known to be unpredictable and must be considered when attempting to establish a *prima facie* case of obviousness. Though one may anticipate that a protein can be expressed using a heterologous expression system, glycosylation and other post-translational modifications of recombinant proteins can be different from that obtained in mammalian systems and therefore expression must be empirically determined for each construct. It is only with the specification in hand that the compound of the instant invention could be known or expected to be active. Further, there is no suggestion in the references cited to combine the teachings of these references as required under MPEP 2143.01.

Accordingly, withdrawal of this rejection is respectfully requested.

VIII. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**VERSION WITH MARKINGS TO SHOW CHANGES MADE**."

Respectfully submitted,

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Date: **October 24, 2002**

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Specification:

Please replace the paragraph at page 4, lines 22-27 with the following paragraph:

--To clone chain 1 and chain 2 succeedingly after H22, a linker oligo was designed. This linker oligo encodes the flexible peptide linker $(Gly_4Ser)_3$ (SEQ ID NO: 5). Unique restriction sites were designed on both sides of the linker creating sticky ends immediately after annealing. The DNA sequence of the linker is described below.--

In the Claims:

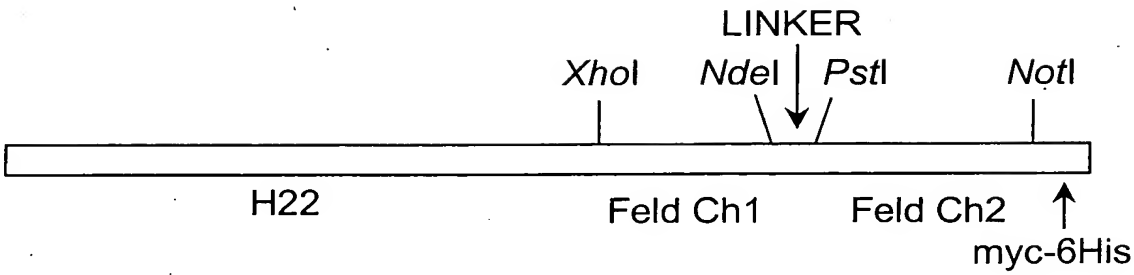
Claim 2 has been canceled.

Claims 1 and 3 have been amended as follows:

1. (amended) A ~~composition~~ compound comprising a baculovirus expressed recombinant Fel dI, wherein the baculovirus expressed recombinant Fel dI comprises chain 1 and chain 2 expressed in series and linked together by a glycine/serine linker of SEQ ID NO: 5.

3. (amended) The ~~composition~~ compound of claim ~~2~~ 1 further comprising a sFv of monoclonal antibody H22 which is a humanized anti-CD64 antibody.

APPROVED BY DRAFTSMAN	O.G. FIG. CLASS	SUBCLASS



H22-Feld CH1 + 2 LINEAR MAP
(1371 bp)

FIG. 1